



01-07-05

IFW

Application No.: 10/615,213

Docket No.: 01946/100G906-US2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS

Examiner: Paul J. KILLOS

**REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT**

MAIL STOP PETITION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants in the above-identified patent application have received a NOTICE OF ABANDONMENT, mailed December 29, 2004 (copy enclosed as Exhibit A), advising that the application has been abandoned due to applicants' alleged failure to timely respond to an Office Action mailed June 23, 2004. The last day to timely file a Response to this Office Action was December 23, 2004 (with a three-month extension of time).

The Patent Office is respectfully advised that on December 23, 2004, Applicants submitted pursuant to 37 C.F.R. § 1.10, *inter alia*, an Amendment in Response to a Non-Final Office Action, a Three Month Request Extension of Time under 37 C.F.R. § 1.136(a), and Check No. 7124 for \$1,020 to cover the three month extension of time fee. In support thereof Applicants enclose the following:

(a) A copy of the originally-deposited postcard listing, *inter alia*: "Amendment in Response to Non-Final Office Action"; "Three Month Request for Extension of Time Under 37

C.F.R. § 1.136(a)"; and "Check No. 7124 for \$1020.00"; showing the number of the "Express Mail" mailing label thereon (EV 382054156) (Exhibit B);

(b) A copy of the Amendment In Response to Non-Final Office Action, a Petition for a Three Month Extension of Time under 37 C.F.R. § 1.136(a), and a Certificate of Express Mailing under 37 C.F.R. § 1.110, as timely filed on December 23, 2004 (Exhibit C);

(c) A copy of the "Express Mail" mailing label showing the "date-in," on the "Express Mail" mailing label (December 23, 2004) entered by the U.S. Postal Service. (Exhibit D);

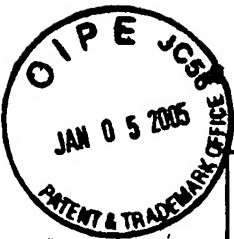
(d) A "Track & Confirm" Report from the U.S. Postal Service, indicating that Express Mail Package EV 382054156 was delivered at 8:31 a.m. on December 27, 2004 to Patent Office, Alexandria, VA 22313, and signed for by M. Boston (Exhibit E);

(f) A declaration signed by Bruce W. Lee, docketing clerk at Darby & Darby P.C., describing the procedure followed by our Docketing Department in the handling of mail to the Patent Office (Exhibit F).

Applicants note that a return post-card has not yet been received by Applicant's counsel. The copies of the correspondence (Exhibits B and C), the "Express Mail" mailing label (Exhibit D), and the official notation entered by the USPS (Exhibit D) are true copies of the originally mailed correspondence, original "Express Mail" mailing label, and official notation entered by the USPS.

We contacted our bank, Citibank, N.A., to determine if Check No. 7124 in the amount of \$1020.00 has cleared. According to Citibank records, there is no indication that Check No. 7124 has cleared, although we understand that it usually takes about two weeks for such records to be updated. Applicants do not submit a second check herewith, since it is believed that Check No. 7124 is in the PTO awaiting processing (or has already been processed). If any additional fees are due, the Commissioner is hereby authorized to charge them to deposit account No. 04-0100.





Application No. (if known): 10/615,213

Attorney Docket No.: 01946/100G906-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. \_\_\_\_\_ in an envelope addressed to:

**EV382053969-US**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on January 5, 2005  
Date

Signature

D B Beck  
Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Request for Withdrawal of Notice of Abandonment (3 pages)  
Exhibits A-F (19 pages)  
Fee Transmittal (1 page)  
Return Postcard



<b>FEE TRANSMITTAL</b> <b>For FY 2005</b>  <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		<b>Complete if Known</b>			
		Application Number	10/615,213		
		Filing Date	July 7, 2003		
		First Named Inventor	Moise Azria		
		Examiner Name	P. J. Killos		
TOTAL AMOUNT OF PAYMENT		(\$)	0.00	Attorney Docket No.	01946/100G906-US2

**METHOD OF PAYMENT** (check all that apply)

☐ Check   ☐ Credit Card   ☐ Money Order   ☐ None   ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account   Deposit Account Number: 04-0100   Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below   ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17   ☒ Credit any overpayments

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): \_\_\_\_\_

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	54,781
Name (Print/Type)	Jason C. Churney	Telephone	(212) 527-7700
		Date	January 5, 2005

Express Mail Label No.	Dated: _____
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UNITED STATES PATENT AND TRADEMARK OFFICE

*Jason Chumney*  
*01946/1806906US2*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,213	07/07/2003	William E. Bay	1946/1G906-US2	8060

7590 12/29/2004

DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER

KILLOS, PAUL J

ART UNIT PAPER NUMBER

DUE: PETITION TO REVIVE  
Docketed on 1/3 by DP for DATE MAILED: 12/29/2004  
Docketed without file ☐  
Attorney \_\_\_\_\_



Please find below and/or attached an Office communication concerning this application or proceeding.



# Notice of Abandonment

Application No.

10/615,213

Examiner

Paul J. Killos

Applicant(s)

BAY ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 23 June 2004.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

Paul J. Killos  
Primary Examiner  
Art Unit: 1625

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



Atty Docket No.: 01946/100G906-US2

Applicant: William E. Bay et al.

Appln: 10/615,213

Filed: Jul. 7, 2003

Title: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING ACTIVE  
AGENTS

**Documents:**

Fee Transmittal for FY 2005 (1 page);

Three Month Request for Extension of Time Under  
37 CFR 1.136(a) (1 page);

Amendment in Response to Non-Final Office Action (8 pages);

Amendment Transmittal Letter (1 page)

Certificate of Express Mailing (1 page); and

Check No. 7124 for \$1,020.00

EV 382054156-us

Via: Express Mail: Airbill No.

Sender Initials: JCC/sjw Date: December 23, 2004

*B.W. Lee*

<b>DARBY &amp; DARBY, P.C.</b>		1-8-210	7124
<b>PATENT OFFICE ACCOUNT</b>			
805 THIRD AVENUE			
NEW YORK, NY 10022		DATE <u>12/23/04</u>	
PAY TO THE ORDER OF	<b>COMMISSIONER OF PATENTS &amp; TRADEMARKS</b>		\$ <u>1020.00</u>
<u>One Thousand Twenty</u>		DOLLARS	<u>84</u>
<b>citibank</b>			
CITIBANK, N.A. BR. #852 153 EAST 53RD STREET NEW YORK, NY 10043		The Citigroup Private Bank	
MEMO	<u>615,213/100G906US2</u>		<i>Gabriella V. Karaszi</i>
⑆021000087⑆		43348071	7124





Application No. (if known): 10/615,213

Attorney Docket No.: 01946/100G906-US2

## Certificate of Express Mailing Under 37 CFR 1.10

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EJ 382054156-US**

on December 23, 2004  
Date

*B.W. Lee*

Signature

*B.W. LEE*

Typed or printed name of person signing Certificate

Registration Number, if applicable \_\_\_\_\_

Telephone Number \_\_\_\_\_

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal for FY 2005 (1 page);

Three Month Request for Extension of Time Under

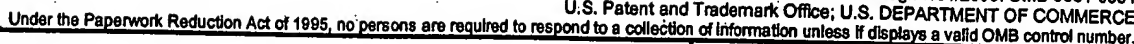
37 CFR 1.136(a) (1 page);

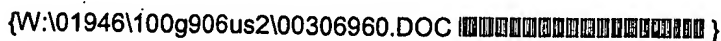
Amendment in Response to Non-Final Office Action ( 8 pages);

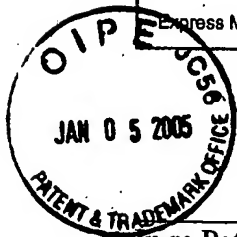
Amendment Transmittal Letter (1 page)

Return Postcard; and

Check No. 724 for \$1,020.00







Express Mail Label No. \_\_\_\_\_ Dated: \_\_\_\_\_

Docket No.: 01946/100G906-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
William E. Bay et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS

Examiner: Paul J. Killos

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

In response to the Office Action mailed June 23, 2004, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

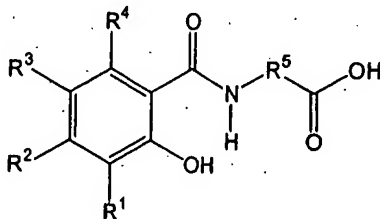
**Remarks** begin on page 7 of this paper.

This submission is accompanied by a request for a three-month extension of time.

**AMENDMENTS TO THE CLAIMS**

Please amend the claims so that they read as follows:

1. (Original): A disodium salt of a delivery agent having the formula



wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

2. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

3. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

4. (Original): The disodium salt of claim 1, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

5. (Original): An ethanol solvate of the disodium salt of claim 1.

6. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

7. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

8. (Original): The ethanol solvate of claim 5, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

9. (Original): A monohydrate of the disodium salt of claim 1.

10. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

11. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

12. (Original): The monohydrate of claim 9, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

13. (Original): A composition comprising at least about 50% by weight of the disodium salt of claim 1, based upon 100% total weight of delivery agent and salts thereof in the composition.

14. (Original): The composition of claim 13, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

15. (Original): A composition comprising:

(a) the disodium salt of claim 1, ethanol solvate thereof, or monohydrate thereof; and

(b) at least one active agent.

16. (Original): The composition of claim 15, wherein the composition comprises at least about 50% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

17. (Original): The composition of claim 16, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

18. (Original): The composition of claim 15, wherein the composition comprises at least about 90% by weight of the monohydrate, based upon 100% total weight of hydrate of the disodium salt of the delivery agent in the composition.

19. (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of growth hormones; human growth hormones; recombinant human growth hormones; bovine growth hormones; porcine growth hormones; growth hormone-releasing hormones; interferons;  $\alpha$ -interferon;  $\beta$ -interferon;  $\gamma$ -interferon; interleukin-1; interleukin-2; insulin; porcine insulin; bovine insulin; human insulin; human recombinant insulin; insulin-like growth factor; IGF-1; heparin; unfractionated heparin; heparinoids; dermatans; chondroitins; low molecular weight heparin; very low molecular weight heparin; ultra low molecular weight heparin; calcitonin; salmon calcitonin; eel calcitonin; human calcitonin; porcine calcitonin; erythropoietin; atrial natriuretic factor; antigens; monoclonal antibodies; somatostatin; protease inhibitors; adrenocorticotropin; gonadotropin releasing hormone; oxytocin; leutinizing-hormone-releasing-hormone; follicle stimulating hormone; glucocerebrosidase; thrombopoietin; filgrastim; prostaglandins; cyclosporin; vasopressin; cromolyn sodium;





Claims 23-28 (Canceled)

29. (New): A method for administering salmon calcitonin to an animal in need thereof, the method comprising administering orally to the animal a composition comprising:

(a) N-(5-chlorosalicyloyl)-8-aminocaprylic acid, wherein N-(5-chlorosalicyloyl)-8-aminocaprylic acid comprises at least about 96% by weight of the disodium salt of N-(5-chlorosalicyloyl)-8-aminocaprylic acid; and

(b) salmon calcitonin.

**REMARKS****Status of the Claims**

Claims 23-28 have been canceled without prejudice or disclaimer. Claim 29 has been added, support for which can be found, for example, on page 8, lines 16-23; and page 5, lines 8-12.

As amended the claims are drawn to two inventions: (1) claims 1-22 are drawn to disodium salts of delivery agents, including ethanol solvates and monohydrates thereof, and compositions and unit dosage forms containing the same; and (2) claim 29 is drawn to a method for administering salmon calcitonin.

**Rejections Under 35 U.S.C. §102**

Claims 1, 2, 4, 5, 7-9 and 11-28 stand rejected as anticipated by WO 96/30036. The Examiner contends that disodium salts are formed in situ when the compounds are treated with sodium hydroxide. Disodium salts are not explicitly disclosed or suggested in WO 96/30036. The claimed compounds have two ionizable sites, one at the carboxyl terminus and one at the 2-hydroxy group on the phenyl ring. Treatment with the amount of sodium hydroxide specified in WO 96/30036 will not form the disodium salt because of the extremely low reaction constant ( $K_a$ ) of the 2-hydroxy group. Therefore WO 96/30036 does not anticipate claims 1, 2, 4, 5, 7-9 and 11-28. Accordingly applicants request withdrawal of this rejection.

In view of the above remarks, applicant believes the pending application is in condition for allowance.

Dated: December 23, 2004

Respectfully submitted,

By 

Jason C. Chumney

Registration No.: 54,781

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant



EV 382054156 US



Customer Copy  
Label 11-1 June 2002

Post Office To Addressee

**ORIGIN (POSTAL USE ONLY)**

PO ZIP Code	10022	Day of Delivery	<input checked="" type="checkbox"/> Next	<input type="checkbox"/> Second	Flat Rate Envelope
Date In	12-23-04	Year	12	Month	23
Time In	8:45	Day	12 Noon	3 PM	Postage
Weight	10.3	ozs.	2nd Day	3rd Day	Return Receipt Fee
No Delivery	<input type="checkbox"/> Weekend	<input type="checkbox"/> Holiday	Initial Alpha	Country Code	COD Fee
CUSTOMER USE ONLY			Acceptance	Initials	Total Postage & Fees
METHOD OF PAYMENT			Express Mail Corporate Acct. No.		

**DELIVERY (POSTAL USE ONLY)**

Delivery Attempt	Time	Mo.	Day	Time	Mo.	Day	Time
<input type="checkbox"/> AM	<input type="checkbox"/> PM	<input type="checkbox"/> AM	<input type="checkbox"/> PM	<input type="checkbox"/> AM	<input type="checkbox"/> PM	<input type="checkbox"/> AM	<input type="checkbox"/> PM
Employee Signature							
Employee Signature							
Employee Signature							

NO DELIVERY ☐

WATER/OVERSIGNATURE ☐ Additional Instructions

Write or Signature to be attached to this label (e.g., "Return to sender")

Signature of Addressee (if required) to be attached to this label (e.g., "Return to sender")

Signature of Addressee (if required) to be attached to this label (e.g., "Return to sender")

**FROM: (PLEASE PRINT)**

DARBY & DARBY PC  
805 3RD AVE FL 21  
NEW YORK NY 10022-7513

**TO: (PLEASE PRINT)**

MAIL STOP  
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PO BOX 1450  
ALEXANDRIA VA 22313-1450

Box: Response

**POSTAL AGENCY ACT NO. 9**

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**POSTAL SERVICE ACT NO. 11**

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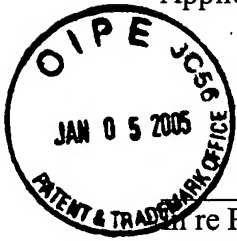
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND  
ETHANOL SOLVATES FOR DELIVERING  
ACTIVE AGENTS

Examiner: Paul J. KILLOS

**DECLARATION OF BRUCE W. LEE**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Bruce W. Lee, declare as follows:

1. I am employed as a Docketing Clerk at Darby & Darby, P.C. I make this declaration in support of the accompanying REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT, which seeks the withdrawal of the NOTICE OF ABANDONMENT mailed on December 29, 2004, in the above-identified application.

2. A true copy of the Notice of Abandonment mailed December 29, 2004 is attached as Exhibit A. The Notice of Abandonment states that the applicant failed to timely file a proper reply to the Office Action mailed on June 23, 2004, and that no reply has been received.

3. A true copy of the Amendment In Response to Non-Final Office Action submitted on December 23, 2004 is attached as Exhibit C. Exhibit C also includes a Petition for a Three Month



knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: January 5, 2005

Respectfully submitted,

By Bruce W. Lee  
Bruce W. Lee  
Docketing Clerk  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 753-6237 (Fax)